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Rev. 07/10/02

When Is Lead a Health Risk?

Predicting a community's risk from lead-contaminated soil is not a simple task, but EPA believes it now has an accurate and scientifically rigorous approach.

In 1988 EPA came to Throop, PA, in search of lead. A battery recycling plant that closed in 1981 had contaminated yards and gardens for 20 years and left an average 2000 ppm of lead in the soil, a concentration high enough to trigger an emergency cleanup according to Agency guidance at the time. More than a hundred yards, gardens, and home interiors were ripped up and cleaned in the $20 million cleanup, which was welcomed by the residents and local doctors who were concerned about the number of congenital anomalies and learning impediments in the local population.

But while EPA was cleaning up Throop, another small town in Colorado was reacting very differently to the Agency's assessment. Mining activity caused the lead contamination that EPA intended to clean up in Aspen's Smuggler Mountain neighborhood in 1986. But the affluent citizens and local doctors were skeptical. When a 1990 survey found low blood lead levels, residents seized on the results as proof that there was no problem. The community's view apparently was vindicated by the findings of an independent technical advisory committee (*1*). Soil lead at Smuggler Mountain, the six experts concluded, did not pose an immediate health problem, and so the EPA cleanup was abandoned in favor of minor precautionary measures.

Although many communities welcome EPA and fight for more cleanup action, not less, Smuggler Mountain has not been alone in rejecting official advice about the hazards of living in a high-lead environment. Even though the soil lead trigger values that previously prompted action have been superseded by use of a predictive model, the controversy over health risk assessment has persisted. Communities such as Palmerton, PA, continue to fight against environmental cleanup, citing low blood lead levels as proof that their health is not at risk.

These discrepancies between blood lead measurements, the most

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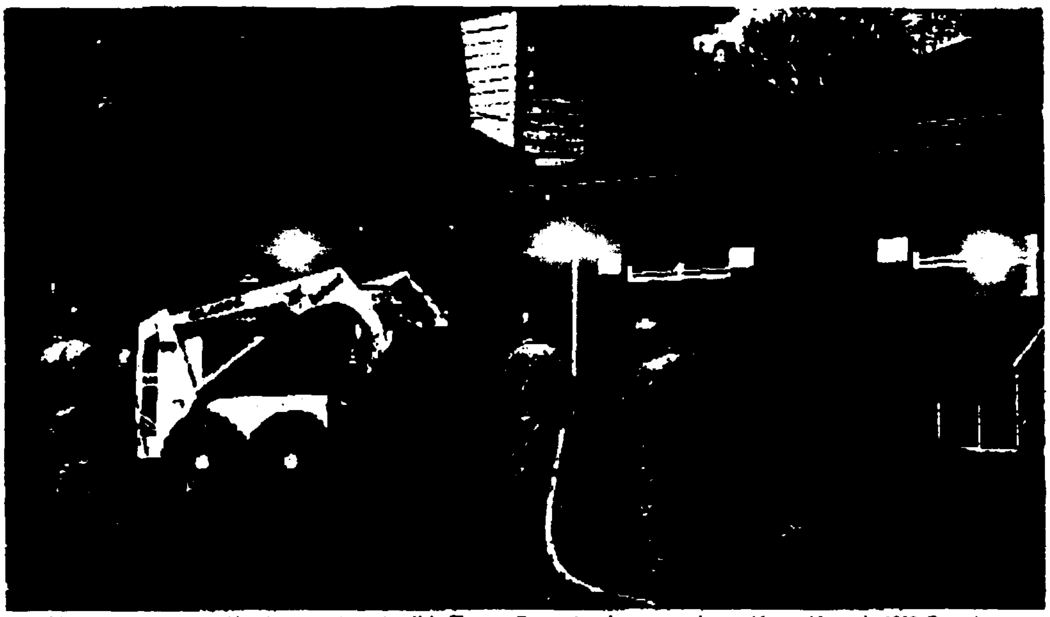

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An EPA-ordered cleanup of lead-contaminated soil in Throop, Pennsylvania, was welcomed by residents in 19[illegible]. But other communities have disputed EPA's health risk assessment of lead exposure and criticized the Agency's assessment methods.

widely accepted biological index of lead exposure, and EPA's model predictions of blood lead levels have called into question the Agency's approach to health assessment at lead-contaminated sites and provoked a major revision in the past year. But as EPA begins to implement the new approach, field trials of the risk model are demonstrating just how difficult it is to accurately predict a community's health risk from lead exposure.

Lead in soil presents a health risk to young children, the population most at risk, because they ingest some soil as part of their hand-to-mouth activity. But how much they ingest depends on many poorly constrained physical and behavioral factors. In turn, the absorption of ingested lead, measured by bioavailability, is controlled by factors that include the physical and chemical characteristics of the lead-bearing mineral and the physiology and metabolism of the child. To make matters more complicated, soil is not the only source of lead; exposure also can come from paint, air, water, and food. And numerous epidemiological studies have shown that children can be at risk without manifesting any obvious symptoms. An increased understanding of these adverse effects prompted the Centers for Disease Control and Prevention (CDC) to lower the acceptable blood lead level three times in the past 20 years, creating an ever lower target for risk assessors (*2*).

Keeping up with science

To address these difficulties, EPA has spent five years improving its predictive model and developing new guidance. Published in February 1994, the revised Integrated Exposure Uptake Biokinetic model (IEUBK; version 0.99d) and the accompanying guidance manual (*3*) change some default parameters and provide new guidance on using the model to estimate blood levels across a community. The model also addresses how to evaluate uncertainty in predicting an individual child's blood lead level. Although the model is being used on all new risk assessments at sites covered under the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act, a validation exercise comparing model predictions with data from different sites is under way. The results from these trials are being used by EPA to refine the model.

An Office of Solid Waste and Emergency Response (OSWER) interim directive published in July 1994 (*4*) specifies that the model should be used by risk assessors on a site-specific basis to find the soil lead level that would result in an estimated probability of no more than 5% that children's blood lead values exceed the 10 µg/dL CDC level of concern. The directive also provides guidance on choosing remedial measures for reducing health risk.

A major change introduced by the model and guidance is its focus on "small-scale" risk assessment. Previous models have assessed community risk most commonly by using an average soil lead concentration to calculate an estimated blood lead distribution for the entire community. However, the manual emphatically rules out broad-brush assessments based on a community-wide average of soil lead concentrations as examples of "garbage in, garbage out" risk assessment. "The home and its surrounding yard is the basic unit for risk analysis because lead exposure for pre-school children commonly occurs within this domain," the manual states.

"We know that there is a great deal of variability in soil lead concentration, and it is therefore not good to take an average," explains Susan Griffin, chair of

How EPA's lead health risk model works

When information is available on the distribution of lead concentrations in a community, EPA's revised Integrated Exposure Uptake Biokinetic (IEUBK) model can estimate the fraction of children that will have blood lead concentrations that exceed a level of concern (currently 10 µg/dL). Four components comprise the model.

(1) *Exposure* relates environmental lead concentrations to age-dependent intake of lead into the gut.

(2) *Absorption* relates the amount of lead in the digestive tract to lead entering the body's circulatory system. Bioavailability enters the calculations here.

(3) *Biokinetics* distributes the lead among seven body reservoirs: plasma, red blood cells, kidney, liver, other soft tissues, trabecular (spongy) bone, and cortical (compact) bone.

(4) The *uncertainty* component is a model for uncertainty in exposure and for population variability in absorption and biokinetics.

The numerical simulation components of the model (exposure, absorption, and biokinetics) yield an estimate of the geometric mean blood lead concentration for a child or children with the same lead exposure. The uncertainty component converts this calculated estimate into a real-world prediction by accounting for differences between individual children: what they do, what they eat, and how their bodies absorb lead. The variability component is represented by a log-normal distribution. The geometric standard deviation, representing the spread of the data, is estimated from blood lead survey data.

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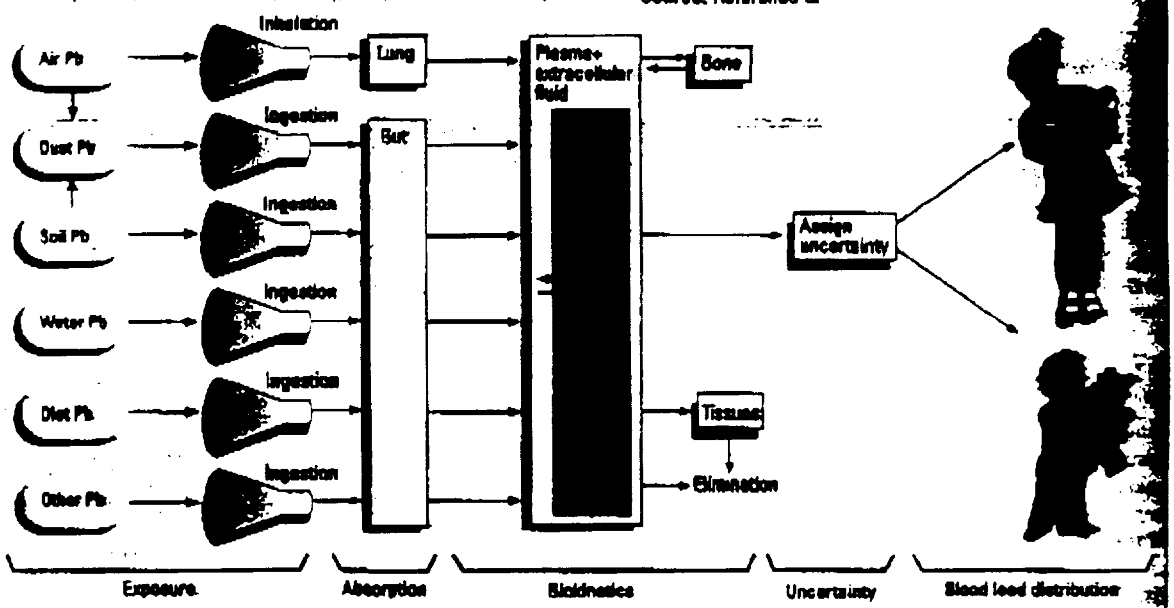


the EPA Technical Review Workgroup for Lead, the group that has coordinated development of the model over the past three years. "That is why we want to work on as small a scale as possible."

However, EPA critics argue that the model and guidance have not changed enough. The new guidance on community-wide estimates and prediction uncertainties is seen as a failed attempt to address differences in individual behavior and community demographics, whereas the new values for parameters such as ingestion rate and bioavailability are still incorrect, critics say. "The model has been through a series of revisions and partial patch-ups," says Craig Boreiko, environmental health manager for the International Lead Zinc Research Organization, an industry-funded group. "These provide some improvement, but they have not been keeping pace with the science. We are waiting to see what the Agency is coming out with in terms of the ongoing validation exercise."

EPA's task has been particularly difficult because the Agency has had to keep up with rapidly increasing scientific knowledge, according to Bruce Means, chief of EPA's toxics integration branch. Operating without a regulation-mandated framework for lead health risk, EPA has had to adapt its approach as the CDC acceptable blood lead level has been repeatedly tightened. The 1985 level of 25 µg/dL dropped to 10 µg/dL in 1991 (*2*). "We operate on a site-specific basis, which means we are more flexible and we have to try for a moving target," says Means.

EPA's guidance for dealing with lead contamination at hazardous sites has evolved since 1989 when it relied heavily on a CDC report suggesting that soil lead concentrations of 500–1000 ppm were accompanied by a rise in blood lead levels. "That range was intended to guide decision makers at our sites," Means says. "But we didn't provide a lot of discussion about the range. I don't mean to imply that what we did was wrong; it's just that there were fewer tools available."

Integrating exposures

An integrated computer model has been the most important new tool to become available. The ancestor of today's IEUBK model was first developed by the EPA Office of Air Quality Planning and Standards to integrate exposure from lead in air, water, soil, dust, diet, and paint, with pharmacokinetic modelling to predict blood lead levels in children. The biokinetic parameters developed for the model in 1985 were extrapolated from long-term feeding studies of infant and juvenile baboons, autopsy data on human children, and other sources. Although the model has become more complex with additional components, and the parameters have been updated, its basic structure remains the same.

EPA's Science Advisory Board (SAB), in its 1991 review of the model, endorsed this structure as a sound and valuable initiative for evaluating and controlling human exposures to lead. But, concerned with the potential for incorrect use of the model, the SAB also recommended more detailed guidance about data acquisition, use of default parameters, and statistical analysis. These recommendations are embodied in the model's new guidance manual.

Supplied with a mix of site-specific and default data, the IEUBK model describes environmental lead intake, absorption, and elimination. Site-specific inputs include the concentrations of lead in soil, dust, water, diet, and air. These are combined with default parameters for ingestion rates to give a total uptake of lead from all sources by the body. The absorption and biokinetic components relate total uptake to blood lead levels. This calculated result is interpreted to be the geometric mean of a lognormal distribution whose variability is characterized by an assumed geometric standard deviation (GSD). The default GSD value is based on epidemiology studies at Superfund sites (3). Although EPA has finished checking the new version's equations and computer code, the comparison with field data is continuing.

Devising an effective lead health risk model is clearly a difficult and complex undertaking, so it is fair to ask whether risk assessments should be based on blood lead surveys instead of computer modeling. After all, blood lead is the most widely used biomarker, and model results (calculated estimates of blood lead) are often judged by comparison to observed data. However, good blood surveys are difficult and expensive. It takes an epidemiologist to design a good blood survey and a specialized laboratory to analyze blood lead. In addition, the short half-life of lead in blood (about 35 days) means that for situations in which lead exposure is variable or intermittent, such as cases of environmental exposure, blood lead provides only limited information (5).

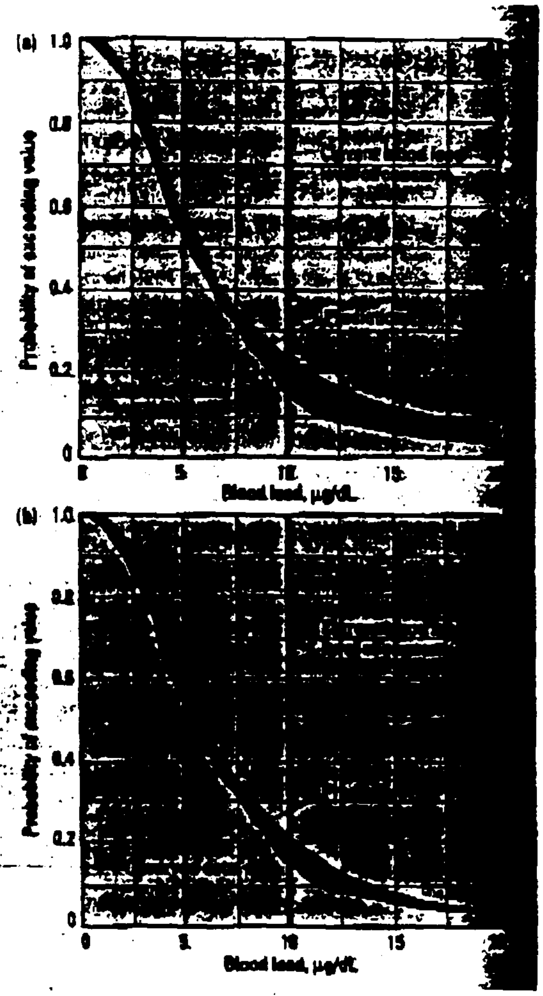
There is also concern that when communities fear a lead poisoning problem, people immediately restrict the activity of their children, causing a change in their contact with lead and an unrepresentative blood lead study, says Paul Mushak, a metal toxicity researcher and consultant in health and chemical sciences in Durham, NC. Indeed, because there

Predictions versus reality: Testing the IEUBK model

EPA is conducting empirical comparisons of the IEUBK model predictions with field studies. These comparisons use existing high-quality data sets which, for each participant, pair measured blood levels with residential environmental lead levels including lead contents of soil, dust, water, and interior and exterior household paint. Demographic and behavioral information is also available. Blood lead distributions generated by entering this data into the model are then compared with the measured blood lead levels by comparing geometric mean blood and the proportion of children expected or observed to have elevated blood lead levels.

Preliminary results for one of these comparisons, at Granite City, IL, were presented at a recent meeting of the Society of Toxicology (5). Community-wide blood lead distributions show good agreement between the observed and predicted data (see Part a of figure). The predicted geometric mean and standard deviation ([illegible] and [illegible]) are good matches with observed values (5.44 and [illegible]).

Although the model overestimates the percentage of children at risk by about 9% (observed value, 15%; predicted value, 24%), EPA analysis indicates that much of the difference between the predicted and observed values at the upper end of the curve (shaded area) may be attributable to "measurement error": the single soil and dust values obtained from each house are insufficient to fully characterize the exposure of children living there. When the effect of this measurement error is taken into account by including results of an analysis of soil and dust variability in individual yards (Part b), the fit between the predicted and observed values at the upper end of the curve improves. EPA staff expect to publish full results of this analysis this year.



Probing bone lead levels with XRF

Throop, PA, is unique among lead-contaminated sites in the United States because L-line X-ray fluorescence (LXRF) was used for the first time to study the long-term lead exposure of the environmentally exposed residential population (5). Three-fourths of the total body lead in children and 95% in adults resides in the bones. X-ray fluorescence (XRF) is a noninvasive technique that uses low-energy X-rays to measure this lead; the measurement reflects cumulative exposure.

There are two XRF techniques and a vigorous debate about the merits of each. LXRF uses partially polarized X-rays to excite X-rays in the 10.5-keV Pb–L region. K-line XRF (KXRF) uses γ-rays from ^{109}Cd to excite 75-keV Pb–K X-rays. Because of the different penetration depths of the respective X-rays, the two methods sample different parts of the bone. LXRF, a sensitive technique used to study lead-poisoned children, looks at the lead only, about a tenth of an inch into the shin bone. Subject to absorption by the overlying skin, LXRF requires careful technique. KXRF, used for more than two decades to measure cumulative occupational exposure to lead, measures lead locked deeper in the shin bone and provides a cross section of bone lead contents. It is less sensitive but more robust than LXRF.

The Throop study established baseline bone lead values in a suburban residential community without unusual lead exposure. The mean bone lead value in 269 Throop residents, 15 ppm, was three times higher than that of the reference suburb, 5 ppm. The study demonstrated that LXRF estimates of bone lead identified individuals at risk for adverse effects of lead, whereas blood lead levels were uninformative (5). However, an as-yet unpublished KXRF study of Throop conducted as support for litigation found no significant differences between the bone lead content of the Throop residents and a different control group.

The current consensus sees two problems in using XRF for routine screening of environmentally exposed populations. XRF is not sufficiently precise to pick out excessively exposed individuals. This problem can be addressed by looking at a large enough group to make the statistics meaningful, as was done in Throop. But ignorance about what factors influence bone lead precludes XRF's general use as an index of lead exposure.

Howard Hu of the Harvard School of Public Health says that current research should improve the utility of bone lead as an index of exposure. "Assuming that research progresses on the behavior of lead in bone under varying conditions of exposure, metabolism, and aging, measurement of lead in bone will become a useful adjunct biomarker for defining a person's lead burden and previous history of lead exposure and possibly their risk for chronic disease," he says.

is often a long time delay between discovery of a problem and any blood lead survey, actions by regulators or public health officials also can modify exposure to lead. For example, at Smuggler Mountain EPA fenced off the most significant source of lead, a 40 ft by 600 ft berm of highly contaminated material, in 1986, significantly modifying exposure to lead years in advance of the 1990 blood lead survey.

However, Robert Bornschein of the University of Cincinnati Department of Environmental Health says that well-designed blood lead surveys are representative. "The whole issue of public awareness is a red herring. Newspaper articles are not enough to change behavior. To do that you need several things: You have to be sure to reach the families with children under six years of age, and you have to get them to do something. But people rarely act on general information because they tend to believe that it doesn't apply to their child."

Although a well-designed blood survey is acknowledged to be of great value, Bornschein says that "as general policy it would be unwise to do blood lead tests regularly. Using a good model is the right way to go." At issue is whether IEUBK is the right model. The consensus seems to be that, though not perfect, the model is a useful tool for estimating risk. The new guidance manual seeks to address some of the model's limitations, such as uncertainty about key parameters and variation caused by behavior and demographics. Chief among these parameters are bioavailability and ingestion rate.

The discrepancies between the blood lead distributions estimated by IEUBK's predecessors and the blood lead survey results have been greater at sites contaminated by mining activity, such as Smuggler Mountain, than at urban sites contaminated by smelters or battery recycling operations, such as Throop. Two special features of mining-related sites that have been implicated as causes of these discrepancies are the bioavailability of lead in various forms of mine waste and the heterogeneous distribution of high soil lead values. Indeed, for mining-related sites, the new directive recommends site-specific assessment of bioavailability and detailed evaluation of the lead distribution.

Bioavailability uncertainties

Bioavailability, a measure of absorption, is in part a function of particle size and speciation. Although estimates of the relative bioavailability of different compounds can produce a ranking order, the model needs absolute bioavailability values applicable to the population most at risk—young children. Other complicating factors include nutrition—a healthy diet reduces bioavailability—and intrinsic biological factors that differ from species to species and even within the same species at different stages of development (6). Because simple bench tests such as solubility fail to measure the behavior of various chemical forms in the body, recent research on bioavailability has focused on animal testing.

Animal tests have used adult and suckling rats, guinea pigs, and weanling swine in an attempt to find a species and a stage of development most relevant in assessing the bioavailability of lead in children. Young children absorb 40–50% of ingested lead, about four times more than adults, who absorb 10–15%; a similar relationship between absorption and development has been demonstrated in other animals. As a result. EPA regional toxicologist Chris Weis advocates experiments with weanling swine because their lead absorption physiology closely resembles that of young children. "By using an immature animal we can address the developmental issue. We think that this is right scientifically, although studies using rats and other animals provide needed information about comparative physiology," he says.

The validity of earlier animal studies has been questioned because they used extremely high doses, 3–4 orders of magnitude higher than what a child is thought to ingest, Weis says. As a result these studies greatly underestimated absorption. Lead absorption in the gut exhibits a curvilinear dose-dependent response. Human data and animal studies indicate that the rate of uptake decreases as the dose increases (6), a relationship consistent with an overload of the active transport mechanism at higher doses. New studies point to higher rates of absorption at lower doses.

Weis believes that a consensus is emerging among academics, industry, and agency researchers about how to design animal experiments. He believes that knowledge gained from animal research will form the basis for designing powerful bench tests that can better predict bioavailability. "We would like to be able to collect a handful of soil, look at it very carefully, possibly using electron microscopy and some compositional analysis, and then predict the bioavailability," he says.

Behavior plays a role

Bioavailability clearly has a bearing on risk assessment at former mining sites, but when the expert panel at Smuggler Mountain reviewed EPA's work, bioavailability alone was not found to be responsible for the overestimate of risk. Citing low soil ingestion rates estimated by Edward Calabrese in 1989 (7), the panel argued that EPA's rate was too high. But the most recent work by Calabrese, who is based at the University of Massachusetts School of Public Health (Amherst), illustrates how elusive an accurate estimate of these parameters can be. He measured the amount of soil ingested by 64 children and found that excessive soil ingestion may be more common than previously thought (8).

In addition to soil ingestion, a great many other important behavioral and demographic variables are beginning to be recognized. "We know that factors such as hand-to-mouth activity, family structure, and parenting style are important," says Bornschein, "and the model currently cannot adjust for these factors." EPA's Susan Griffin acknowledges the importance of such information and says that there are plans to incorporate behavioral and demographic site-specific data into future versions of the model.

New results from EPA's ongoing validation studies, released in March at a meeting of the Society of Toxicology in Baltimore, MD, attest to the importance of incorporating more site-specific data into the model. Data from a Granite City, IL, study relating environmental and blood lead levels on an individual basis were compared with IEUBK predictions based on the same environmental data (9). The match between actual blood levels and model predictions was poor when the model was run with the only site-specific input being soil lead values. However, when the default parameters were modified to take into account site-specific behavioral and sociodemographic information, the match between the data and the model predictions significantly improved.

EPA's new guidance requires site managers and risk assessors to thoroughly delineate the lead contamination at hazardous sites so that they can conduct their analysis on the scale of households and neighborhoods. This emphasis on small-scale risk assessment is certainly a necessary transitional step toward a more realistic, science-based appraisal of risk. But this improvement, the aim of model developers and researchers, comes to the user community without clear guidance on how to apply the model results to calculate a soil lead cleanup level.

The small-scale modeling approach embodied in IEUBK will need to incorporate site-specific behavioral and demographic factors, but developers are still working on these improvements. In the meantime, the OSWER directive specifies a risk target: an estimated risk of no more than 5% of exceeding the CDC level of concern. But the directive fails to clearly identify to whom the analysis applies. According to the directive it is "a typical (or hypothetical) child or group of similarly exposed children."

Field workers must grapple with this ambiguous advice, but Bornschein cautions that although the new guidance marks a transition to more accurate and precise risk assessment, it strips away the statistical power of the current model. "Right now the means predicted by the model are pretty good. But down at the individual level, the correlation is very weak. If the model is used to determine cleanups on a house-to-house basis, then it will miss at both ends. They'll clean up some households that don't need it but, more importantly, they'll miss others that do."

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